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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,201	05/15/2007	Jean-Pierre Sachetto	SACH3001/ESS	8441

23364 7590 10/09/2008

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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,201	SACHETTO ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-22,25,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-22,25,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-10, 13-22, 25, and 30-31 are pending and the subject of this Office Action.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

First 112, First Paragraph First Rejection

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are enabled for the treatment of chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, and bipolar disorder. However, the claimed prophylaxis of the same, *supra*, is not supported by the specification. As a result, the effect of performing the invention by one skilled in the art would be that of undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986)

and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in organic chemistry is high, the results of experiments to discover treatments for the illnesses and conditions recited in claim 30, is unpredictable. While all of the Wands factors are considered, a sufficient amount for a *prima facie* case is discussed below.

As noted previously, the applicant documentation to support the treatment of the referenced conditions as set forth in claim 30 (Specification, pages 6 and 8). Applicant argues that under the current status of the law, Applicant does not have to prove or show that the invention is effective for prophylaxis. And notably, the applicant has failed to enable based on the disclosures in the specification and as it stands, there is no known cure, for example, for bipolar disorder. See U.S. Patent No. 6555316, Col. 5, lines 13-14. Therefore, the prophylaxis in the claims is not enabled because the same would require undue experimentation.

First 112, First Paragraph Second Rejection

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that their amendment to claim 30 to incorporate language defining neoplastic diseases as those treatable by the administration of omega-3-polyunsaturated fatty acid and an antineoplastic agent from a list provided in the specification corrects the deficiency stated as the reason for this rejection. It does not, however.

The arguments in support of this rejection as stated in the Office Action of 28 January 2008 are incorporated herein by reference in their entirety.

As noted previously, for the various known cancer types, there is not one specific chemotherapeutic agent or agents that is effective for each and every type of cancer or tumor, which is the subject matter encompassed by the present claims. Given the state of the art as set forth above, the artisan is currently unaware of any one particular anti-cancer agent, or combinations thereof, that is effective in treating all known types of cancer.

The lack of significant guidance from the present specification or prior art with regard to the treatment of all cancers or tumors in a patient with any known anti-cancer or anti-tumor formulation imparts a significant degree of unpredictability in practicing the invention as presently claimed. The guidance given by the specification is to generally administer the claimed active agent(s) to treat cancers or tumors broadly. None of the examples in the present specification address the treatment of any particular cancer type, much less cancers in general. And the new language incorporated into claim 30 merely

describes a treatment regime that may be used for multiple disorders without clear metes and bounds.

The complex nature of the subject matter to which the present claims are directed is exacerbated by the breadth of the claim. The claims are extremely broad due to the vast number of possible cancer/tumor types represented by the term "neoplastic disease" and the new amendment does not sufficiently compensate for this breadth. Given that the art fails to recognize and Applicant has failed to demonstrate that all known cancers/tumors could actually be treated, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 13-22 (composition claims) and 30-31 (method claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 17 (composition claims) and 13-16 of U.S. Patent No. 5,792,795 for the reasons made of record in this office's action of 28 January 2008. Applicants argue that the rejection is not well-founded, because the present invention is based on the unexpected observation that soft gelatin capsules containing PUFAs in free acid form in which the gelatin is Type A are significantly more stable than equivalent capsules made from Type B and thus, the characterizing feature of the present invention is the specific choice of gelatin from which to make soft gelatin capsules.

The same argument was made applicable over the rejection of claims 1-10 and 13-22 (composition claims) and 30-31 (method claims) on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 5,948,818.

Applicants arguments are considered but allegations lacking sufficient factual support, and they do not take the place of objection evidence. It is well known in the art that Type A gelatin and Type B gelatin formation are both by the same process, the partial hydrolysis of collagenous material and regardless of their points of derivation, both Type A and Type B gelatins and blends thereof can be used to obtain a gelatin with the requisite viscosity and bloom strength. See U.S. Patent No. 4,935,243 (Col. 3, lines 20-46)[hereinafter referred to as "Borkan et al"].

In light of the foregoing, the rejection of record is sustained.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13-22, 25, and 30-31 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as "Breivik et al"](the reference is being considered in its totality) in view of Borkan et al.

The teachings of Brevik et al from this Office's Action of 28 January 2008 are incorporated herein by reference in their entirety. Applicants argue that there is no disclosure in Brevik et al of the use of any gelatin and most particularly, the use of Type A gelatin.

As noted prior, Breivik et al do not disclose specifically soft gelatin capsules comprising fish gelatin, bovine gelatin and/or porcine gelatin. Nor do they disclose

explicitly time release capsules. However, the adjustment of particular conventional working conditions such as these are mere matters of routine optimization and judicious selection well within the purview of one of ordinary skill in the art.

And furthermore, Borkan et al teach that Type A gelatin and Type B gelatin formation are both by the same process, the partial hydrolysis of collagenous material and regardless of their points of derivation, both Type A and Type B gelatins and blends thereof can be used to obtain a gelatin with the requisite viscosity and bloom strength. (Col. 3, lines 20-46). Furthermore, gelatin types, between Type A and Type B are interchangeable and most often, plasticizers are added to produce soft gelatin that is chewable and the same has been known as early as the 1990s, based on the discloses herein (Col. 3, lines 40-46).

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to conclude that the making and administration of a soft gelatin capsule containing EPA and DHA would be effective in the treatment of hypertriglyceridaemia.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199

(IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614